

acid). No new matter has been added by the proposed amendments and Applicants respectfully request entry thereof. By these proposed amendments, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which the Applicants are entitled. *Cf. Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

Claims 2-13, 21, 31-35, 39-40, 42-116, and 123 have been withdrawn from consideration in either this Reply or a previous Reply without prejudice to, or disclaimer of, the subject matter thereof. Applicants reserve the right to file continuation applications directed to the subject matter of any claim withdrawn from consideration for any reason.

Claim Objections under 37 C.F.R. § 1.75(c)

Claims 2-13, 39-40, and 42-52 were objected to under 37 C.F.R. § 1.75(c). Paper No. 8 at page 2. Specifically, the Examiner alleged that the claims were in improper dependent form "for failing to further limit the subject matter of a previous claim." *Id.* Applicants respectfully traverse.

Without acquiescing to the Examiner's objections, and solely in order to promote the progress of the present application, Applicants have withdrawn claims 2-13, 39-40, and 42-52 from consideration without prejudice to, or disclaimer of, the subject matter thereof. As noted above, Applicants reserve the right to file continuation applications directed to the subject matter of any claim withdrawn from consideration for any reason. Applicants respectfully submit that the withdrawals obviate the Examiner's objections.

Accordingly, Applicants respectfully reconsideration and withdrawal of the pending objections under 37 C.F.R. § 1.75(c).

Rejections under 35 U.S.C. § 102(a or e)

The Examiner rejected claims 1-15, 18, 20-30, 36-52, 117-120, and 122-136 under 35 U.S.C. § 102(a or e). Paper No. 8 at page 3. Specifically, the Examiner alleged that the claims were anticipated by U.S. Patent No. 5,976,568 ("Riley"). *Id.* Applicants respectfully traverse.

In order to support an anticipation rejection under 35 U.S.C. § 102, the Examiner must illustrate that each and every element of a claimed invention was disclosed within a single prior art reference. *In re Bond*, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990).

Applicants direct the attention of the Examiner to the fact that independent claims 37 and 134 as filed within Paper No. 6 define the claimed compositions as having, *inter alia*, about 2.25 mg to about 2.75 mg folic acid. Applicants submit that Riley fails to teach each and every element of independent claims 37 and 134. Specifically, Riley fails to teach any composition comprising about 2.25 mg to about 2.75 mg folic acid. As such, Riley fails to anticipate the inventions within the scope of independent claims 37, 134, and all claims dependent from 37 and 134.

Further, the attention of the Examiner is respectfully directed to the fact that Applicants propose to amend independent claims 1 and 117 such that the claims define compositions as having, *inter alia*, at least 800 micrograms of folic acid. Riley fails to teach compositions comprising more than 800 micrograms of folic acid. Thus, given that Riley fails to teach each and every element of proposed claims 1 and 117, Applicants submit that the proposed amendments render the rejections of independent claims 1 and 117 and all claims dependent therefrom moot.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the pending rejections under 35 U.S.C. § 102(a or e).

Rejections under 35 U.S.C. § 103(a)

Claims 1-30, 36-52, and 117-136 stand rejected under 35 U.S.C. § 103(a). Paper No. 8 at pages 4-5. Specifically, the Examiner asserts that the claims are unpatentable over Riley. *Id.* Applicants respectfully traverse.

To maintain a proper rejection under 35 U.S.C. § 103, the USPTO must meet three conditions. First, the USPTO must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the USPTO must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an Applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991).

As a preliminary matter, Applicants respectfully assert that the Examiner has failed to establish a *prima facie* case of obviousness. First, the Examiner has failed to specifically demonstrate how Riley suggested to one of ordinary skill in the art the compositions of independent claims 37 and 134 and proposed independent claims 1 and 117. While the

Examiner has provided a listing of components of a composition allegedly taught by Riley (Paper No. 8 at page 4), the mere listing fails to relate the claimed ranges and fails to relate how or why one of ordinary skill in the art would have manipulated the ranges to produce the claimed inventions. Second, the Examiner has failed to relate how Riley would have provided one of ordinary skill in the art with a reasonable expectation of success in producing the compositions of independent claims 37 and 134 and proposed independent claims 1 and 117. Applicants note that the Examiner has provided no support beyond improper and conclusory arguments for the proposition that one of ordinary skill in the art would have been able to produce the claimed inventions relying solely upon the alleged disclosures of Riley. Finally, the Examiner's comments appear to be based upon nothing more than impermissible hindsight reconstruction. The Examiner appears to have utilized as a framework nothing more than the disclosures of the present application in constructing the arguments related to obviousness. With respect to the Examiner's comments regarding zinc and chromium, for example, the Examiner points to no reference other than the present application that discloses a composition comprising what the Examiner deems the "preferred salts of zinc and chromium." Paper No. 8 at page 4.

In addition, the attention of the Examiner is respectfully directed to the fact that Applicants, without acquiescing to the Examiner's rejections under 35 U.S.C. § 103(a), propose to amend independent claims 1 and 117 such that the claims define compositions as having, *inter alia*, at least 800 micrograms of folic acid. Riley fails to teach or suggest compositions comprising more than 800 micrograms of folic acid. Thus, Applicants submit that the proposed amendments render the rejections under 35 U.S.C. § 103(a) of independent claims 1 and 117 moot.

Further, Applicants direct the attention of the Examiner to the fact that independent claims 37 and 134 as filed within Paper No. 6 define the claimed compositions as having, *inter alia*, about 2.25 mg to about 2.75 mg folic acid. Applicants submit that Riley fails to teach or suggest each and every element of independent claims 37 and 134. Specifically, Riley fails to teach or suggest any composition comprising about 2.25 mg to about 2.75 mg folic acid. As such, Riley fails to render obvious the inventions within the scope of independent claims 37 and 134.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the pending rejections under 35 U.S.C. § 103(a).


CONCLUSION

The Applicants respectfully request that the Examiner consider the present remarks and reconsider and withdraw all pending rejections. Should there be any further matters requiring consideration, the Examiner is invited to contact the undersigned counsel.

If there are any further fees due in connection with the filing of the present reply, please charge the fees to undersigned's Deposit Account No. 50-1067. If a fee is required for an extension of time not accounted for, such an extension is requested and the fee should also be charged to undersigned's deposit account.

Respectfully submitted,

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Don J. Pelto
Reg. No. 33,754

McKenna Long & Aldridge LLP
1900 K Street NW
Washington, D.C. 20006-1108
Telephone: 202.496.7500
Facsimile: 202.496.7756

Claim Amendments

1. (twice amended) A composition for supplementing nutritional deficiencies in a patient or person in need thereof, comprising about 45 mg to about 55 mg vitamin C, about 31.5 IU to about 38.5 IU vitamin E, about 180 µg to about 220 µg chromium, about 63 µg to about 77 µg selenium, about 18 mg to about 22 mg zinc, B-complex other than folic acid, and [B-complex]at least 800 µg folic acid, wherein said composition is administerable to a patient or person.

20. (amended) The composition of claim 1, wherein said B-complex other than folic acid is one or more vitamins selected from the group consisting of pantothenic acid, cyanocobalamin, niacin, pyridoxine, riboflavin, thiamine, [folic acid,] and biotin.

117. (amended) A composition for supplementing nutritional deficiencies in a patient or person in need thereof, comprising about 45 mg to about 55 mg vitamin C, about 31.5 IU to about 38.5 IU vitamin E, about 63 µg to about 77 µg selenium, about 18 mg to about 22 mg zinc, B-complex other than folic acid, and [B-complex]at least 800 µg folic acid, wherein said composition is administerable to a patient or person.

122. (amended) The composition of claim 117, wherein said B-complex other than folic acid is one or more vitamins selected from the group consisting of pantothenic acid, cyanocobalamin, niacin, pyridoxine, riboflavin, thiamine, [folic acid,] and biotin, wherein said composition is administerable to a patient or person.